# CONTRACT CONCEPT REVIEW

**Board of Scientific Counselors Meeting**
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**Title:** **Preparation of the Report on Carcinogens**

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## I. Purpose

The purpose of the proposed contract is to provide support for the preparation of the Report on Carcinogens (RoC).

## II. Background

The RoC is a congressionally-mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as "substances") that may pose a hazard to human health by virtue of their carcinogenicity. Substances are listed in the report as either *known to be* or *reasonably anticipated to be a human carcinogen*. The National Toxicology Program (NTP) prepares the RoC on behalf of the Secretary of Health and Human Services. The RoC is considered to be an authoritative source by (1) California's Safe Drinking Water and Toxic Enforcement Act of 1986 initiative, or Proposition 65, and (2) the OSHA Hazard Communication Standard. Substances considered by the NTP for possible listing or delisting in the RoC, are evaluated by a rigorous scientific review process with multiple opportunities for public comment. To date, a total of 11 RoCs have been published with the latest edition, the 11th RoC, being released on January 31, 2005.

The NTP was established in 1978 to: (1) coordinate toxicology testing programs within the federal government, (2) strengthen the science base in toxicology, (3) develop and validate improved testing methods, and (4) provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public.

## III. Objectives

The goal of this contract is to provide support of NTP hazard identification activities targeted toward the prevention of diseases or adverse effects caused by environmental exposure to chemical or physical agents. The specific objective is to procure assistance in preparing the RoC, which includes support for the review process, and for preparing the report. The RoC is a compilation of substance profiles for each listing, and relevant tables, appendices, and indexes related to RoC activities. A substance profile summarizes the following information for a listed substance: its carcinogenicity in humans and animals, the biological mechanisms by which it causes cancer, potential for human exposure, and Federal regulations to limit exposure. Each new edition of the RoC contains substance profiles for substances previously listed in the RoC, and profiles for newly listed substances.

The proposed contract would include the following activities:

- Support for the preparation of RoC documents such as the draft background document and the pre-publication draft of the RoC. Contract support is needed for identifying and summarizing regulatory and exposure information, conducting literature searches of the peer review literature, and summarizing the experimental data. The draft background document describes data on a substance on its (1) use and production, (2) exposure to the general population from environmental sources and in the workplace, and (3) human epidemiology, experimental animals, genotoxicity and mechanistic studies from the publicly available peer-reviewed literature. Support is also needed to update the information (primarily exposure and regulatory) in the substance profiles for previously listed substances and to update information in the appendices and tables in the RoC.
- Administrative and logistic support for convening expert panel meetings. For each substance under review, an expert panel is convened to provide advice concerning the potential carcinogenicity of the substance.

## IV. Priority

The preparation of the RoC is considered high priority because it is a congressionally-mandated document that serves to inform the public, scientists, and health care professionals on substances that pose a hazard to human health by virtue of their carcinogenicity. It contributes to the NIEHS mission to reduce the burden of human illness and disabilities.